

Remarks

Upon entry of the foregoing amendment, claims 1-39, 43, and 52-61 are pending in the application. The Office Action misidentified the status of certain claims. The correct status is that claims 1-25, 51, and 53-55 are withdrawn. Claims 26-39, 43, 52, and 56, as well as newly added 57-61, are pending and not withdrawn.

Amendments

Claim 26 has been amended to clarify that the microchip device includes a plurality of reservoirs that are located *in the substrate* and that the reservoir contents are disposed *in* these reservoirs. Claim 26 also has been amended to specify that the microchip device includes *means for selectively controlling* release or exposure of the reservoir contents. Support for these amendments is found throughout the specification, for example, at page 3, lines 8-11 and page 5, lines 10-13. Claim 27 has been amended to conform to amended claim 26. Support for the amendment is found at least at page 12, lines 25-28.

Claim 56 has been amended for clarity. Support for the amendment is found throughout the specification, for example, at page 16, lines 5-6. New claims 57-61 have been added. Support for these amendments can be found, for example, at page 6, line 31 to page 7, line 1; page 7, lines 8-15 and 24-27; page 11, line 9-18 and 29; and page 12, lines 25-30. No new matter has been added.

Rejections Under 35 U.S.C. § 102

Claims 26-39, 43, 51, and 56 were rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent Application Publication No. 2002/0082665 to Haller et al. (hereinafter “Haller”)

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or by U.S. Patent No. 6,757,650 to Fischer et al (hereinafter "Fischer"). Applicants respectfully traverse these rejections.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, is a single prior art reference." Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631 (Fed. Cir. 1987). A claim element is not "inherent" in the disclosure of a prior art reference unless extrinsic evidence clearly shows that missing descriptive matter is **necessarily** present in the thing described in the reference. In re Robertson, 49 U.S.P.Q. 1949 (Fed. Cir. 1999). "Inherency, however, may not be established by mere probabilities or possibilities" (49 U.S.P.Q. at 1950-51).

Fischer Is Not Prior Art

Fischer is not available as a prior art reference against the present application. Fischer is not a 102(e) reference. The Examiner's attention is directed to M.P.E.P. § 706.02(f)(1), in particular Example 9 and Flowchart I on pages 700-36 to 700-38. Because the international application (PCT/EP99/02425 filed April 9, 1999) to which Fischer claims priority was filed *before* November 29, 2000, the 102(e) date is the § 371(c)(1), (2), and (4) date or the § 111 date. Fischer has a § 111 date of October 10, 2000. (It does not have a § 371 date.) Therefore, Fischer's 102(e) date is October 10, 2000.

Applicant's priority date is also October 10, 2000. Fischer thus is not prior and cannot be applied as a 102(e) prior art reference. Accordingly, the rejection of Applicants' claims over Fischer is improper and must be withdrawn.

If Fischer Were Prior Art, It Fails to Disclose Applicants' Claimed Systems

Even if Fischer were available as prior art, it clearly does not teach all of the elements and limitations defining Applicants' claimed systems. For instance, Fischer fails to disclose a system or device utilizing *wireless telemetry*, and the reference plainly fails to disclose an *implantable* device or a device having a *plurality* of reservoirs *in* a substrate.

Haller Fails to Disclose Applicants' Claimed Systems

Haller discloses a medical information communication system for monitoring the performance of an implantable medical device (IMD) implanted within a body of a patient or for remotely delivering a therapy to the patient through the IMD (abstract). Haller discloses that the IMD can be a "implantable drug pump or dispenser" (¶ 0167, 0241).

However, Haller clearly fails to disclose a microchip device or implantable device having a substrate with a *plurality* of reservoirs located therein, as required by Applicants' claims 26 and 56. Furthermore, Haller fails to disclose an implantable medical device that includes means for selectively controlling release or exposure of reservoir contents stored in each of the *multiple* reservoirs. Haller also fails to disclose reservoirs having reservoir caps, as required by Applicants' claims 36 and 56-61. In addition, Haller fails to disclose reservoir contents that comprise an immobilized enzyme, as required by Applicants' claims 52 and 58.

In summary, Haller clearly does not teach all of the elements and limitations defining Applicants' claimed systems. Accordingly, the rejection of Applicants' claims over Haller is improper and must be withdrawn.

Rejection Under 35 U.S.C. § 103

Claims 26-39, 43, 51 [sic, 52], and 56 were rejected under 35 U.S.C. § 103(a) being obvious over US Patent No. 5,971,931 to Raff (hereinafter “Raff). Applicants respectfully traverse this rejection.

The Court of Appeals for the Federal Circuit has explained that to sustain an obviousness rejection “*particular findings* must be made as to the *reason* the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination *in the manner claimed.*” In re Kotzab, 217 F.3d 1365, 1371 (Fed. Cir. 2000) (emphasis added). As detailed below, the Office Action fails to articulate the required “particular finding” to support a *prima facie* case of obviousness.

Raff discloses a system that includes (1) an earpiece for sensing blood pressure and a transceiver for transmitting the measured pressure, (2) a wearable platform for receiving and displaying sensed information, (3) a monitoring station, (4) EKG sensors, and (5) an eyepiece with spectrophotometric sensing that can transmit biochemical information from the retina to the platform, (6) an implanted subcutaneous syringe that can inject drugs at the instruction of the platform, and (7) environmental sensors. Col. 1, Lines 48-64. Raff teaches that the syringe “contains a reusable drug reservoir, a pump and subcutaneous nozzle” (Col. 3, Lines 35-36).

Raff fails, however, to disclose or suggest Applicants’ claimed systems. For example, Raff fails to disclose or remotely suggest a microchip device or implantable device having a *substrate with a plurality of reservoirs located therein*, as required by Applicants’ claims 26 and 56. Furthermore, nothing in Raff at all suggests a device with multiple reservoirs covered by *reservoir caps*, as required by Applicants’ claims 36 and 56-61. In addition, Raff fails to

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disclose or suggest reservoir contents that comprise an *immobilized enzyme*, as required by Applicants' claims 52 and 58.

The Office Action's analysis is conclusory and fails to properly consider the Raff reference as a whole. One skilled in the art would not have been motivated to "duplicate the reservoirs" because Raff teaches that the drug reservoir is "reusable" which is to say, refillable. For an implantable device of any kind, one skilled in the art would not be motivated to duplicate the reservoir to a drug pump because the skilled artisan would want to keep the device as small as possible for minimal impact on the patient. Providing two discrete reservoir would be unnecessary and require either a second pump or additional valving and piping to switch the source reservoir being pumped—both of these design scenarios would be undesirably complicated and unnecessarily require a larger device. In sum, only in hindsight of Applicants' disclosure would one of ordinary skill in the art be led to modify and extend the disclosure of Raff, to somehow derive the presently claimed systems.

For the foregoing reasons, Applicants submit that the claims as amended are novel and nonobvious over the prior art of record. Allowance of claims 26-39, 43, 52, and 56-61 is therefore respectfully solicited.

Respectfully submitted,



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